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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,167	12/19/2001	Patricia A. Billing-Medel	6068.US.D1	5842

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EXAMINER
ZITOMER, STEPHANIE W

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,167	BILLING-MEDEL ET AL.	
	Examiner	Art Unit	
	Stephanie Zitomer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-10,12-14 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10,12-14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application status

1. Receipt of the Preliminary Amendment filed December 19, 2001 with the filing of the application is acknowledged. According to clims cancellations therein, claims 7-10, 12-14 and 16 are pending.

Informalities: Objection to the disclosure

2. The disclosure is objected to because of the following informalities: The specification and claims are not in compliance with 37 CFR 821 which requires that the sequence designator be **SEQ ID NO:**. Appropriate correction is required.

Rejection under 35 U.S.C. 112, first paragraph: Lack of written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 13 and 14 are drawn to methods of treating an individual with an immunogenic polypeptide or fragment of the CS193 polypeptide and treating an individual via gene therapy with a plasmid comprising a polynucleotide sequence encoding at least one CS193 epitope, respectively. In common parlance, "individual" refers to a person, a human, and while the word is not defined in the claims or in the specification, "human" is identified along with animals such as mouse, rabbit and goat as subjects for producing antibodies although the animals are preferred (page 44, lines 3-6). Antibodies as therapy are mentioned at page 33 (lines 30-33) and *in vivo* antigen expression via inoculation of mice or rabbits

(preferred animals) with an expression plasmid carrying CS193 cDNA sequences is disclosed in Example 13 (page 72) whereas administration of a plasmid expressing a CS193 epitope to a human is not described. Furthermore, the specification fails to establish any useful result of the claimed methods of treating humans to generate CS193 antibodies. On the contrary, assays employing antibodies to CS193 peptides for detection of CS193 protein are described in several passages, notably Example 19 (pages 81-82). In this Example, detection of CS193 antigen in a patient sample provides a useful marker of GI tract disease, especially cancer. Additionally, the specification fails to describe such treatment protocols as CS193 protein dosages, routes of administration, duration of therapy, etc. In addition to enablement the first paragraph of 112 requires a "written description". As set forth by the Court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. For the foregoing reasons it is clear that applicant was not in possession of the methods of treating humans with CS193 protein to produce antibodies thereto at the time the claimed invention was made.

It is suggested that this rejection may be overcome by directing claims 13 and 14 to methods for producing antibodies in animals and recovering the antibodies, e.g., by harvesting antisera as in Examples 13 and 14.

Rejection under 35 U.S.C. 112, second paragraph: Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 10 and 14 are indefinite because the phrase "epitope derived from" (emphasis added) an amino acid sequence or a polypeptide is not defined in the claims or in the specification. A polynucleotide "derived fom" a "designated sequence" is described at page 11, the

paragraph bridging page 12, and "epitope" is described as an "antigenic determinant of a polypeptide" at page 16, lines 6-15. However, neither of these descriptions specifically defines the meaning of "epitope derived from" in the contexts of claims 10 and 14. It is suggested to specifically define the meaning of the phrase in the claims.

Rejection under 35 U.S.C.102(b): Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 7-10, 12 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Cunningham et al. (J. Biol. Chem. (1995) 270(52):31016-31026). Regarding claims 7-9, Cunningham et al. disclose the claimed polypeptide having at least 60% identity with an amino acid sequence selected from the group consisting of SEQ ID NOS:41-49 and fragments thereof at pages 31018-31019. "Fragments" may be as small as one or two or three nucleotides. The recitations in claims 8 and 9 of how the polypeptide is made do not distinguish the polypeptide of claim 7 over the prior art because it is the same polypeptide regardless of how it is made. Nevertheless, Cunningham et al. disclose the embodiment of claim 8 herein the polypeptide is made by recombinant techniques at page 31019, second and third full paragraphs while that of claim 9 wherein the polypeptide is produced by synthetic techniques is disclosed at page 31017, last paragraph, continued on page 31019.

Regarding claim 10, the antibody which specifically binds at least one CS193 epitope derive from an amino acid sequence having at least 50% identity to a sequence selected from SEQ ID NOS:41-49 is disclosed by Cunningham et al. (page 31021, first full paragraph).

Regarding claim 12, the method for producing a polypeptide comprising at least one CS193 epitope by incubating host cells transfected with an expression vector containing a polynucleotide sequence encoding a polypeptide having at least 60% identity with a sequence selected from SEQ ID NOS:41-49 is disclosed in Cunningham et al. (page 31019, first full paragraph).

Regarding claim 16, the composition of matter comprising a polypeptide containing at least one CS193 epitope, the polypeptide having at least 60% identity with a sequence selected from SEQ ID NOS:41-49 is disclosed by Cunningham et al. (page 31019, third full paragraph).

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 10:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact LIE Chantae Dessau at 703-605-1237.

S. Zitomer
Stephanie Zitomer, Ph.D.
August 11, 2003

STEPHANIE W. ZITOMER
PRIMARY EXAMINER